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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/522,081

02/03/2006

Cinzia Lanzi

200144.415USPC

7569

32516 7590 05/15/2008

DONALD W. WYATT
CELL THERAPEUTICS, INC.
501 ELLIOTT AVENUE WEST, #400
SEATTLE, WA 98119

EXAMINER

KUDLA, JOSEPH S

ART UNIT

PAPER NUMBER

1611

MAIL DATE

DELIVERY MODE

05/15/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/522,081	Applicant(s) LANZI ET AL.	
	Examiner JOSEPH S. KUDLA	Art Unit 1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) 1-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 19-24 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

Foreword

1. Applicant's phone message, received April 25, 2008, is acknowledged. Upon further review of the Election/Restriction correspondence, filed December 12, 2007, the Examiner has determined the Restriction to be improper. Accordingly, the Restriction/Election correspondence, filed December 12, 2007, is rescinded. Below, Applicant will find the new/current Restriction/Election of Species required before examination of the Application can proceed.

Non-Statutory Subject Matter

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

2. Claims 1-18 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claims 1-18 provide for "The use of the compound 1,3-dihydro-5,6-dimethoxy-3-[(4-hydroxyphenyl)methylene]-2H-indol-2-one or of non-toxic salts or isomers thereof for the preparation of a medicament..." but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending

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to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced. Instant claims 1-18 are directed towards a non-statutory class of invention and, as such, will be withdrawn from consideration in the Restriction/Election of Species below.

Election/Restrictions

3. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 19, drawn to a pharmaceutical composition containing as active ingredient the compound 1,3-dihydro-5,6-dimethoxy-3- [(4-hydroxyphenyl)methylene]-2H- indol-2-one or a pharmaceutically acceptable salt thereof in combination with a pharmaceutically acceptable carrier, excipient or diluent.

Group II, claim(s) 20, drawn to a pharmaceutical composition containing 1,3-dihydro-5,6-dimethoxy-3- [(4 hydroxyphenyl)methylene]-2H- indol-2-one and a pharmaceutically acceptable carrier or diluent suitable for oral or parenteral administration.

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Group III, claim(s) 21-24, drawn to a pharmaceutical composition and a kit containing 1,3-dihydro-5,6-dimethoxy-3- [(4 hydroxyphenyl)methylene]-2H- indol-2-one and a pharmaceutically acceptable carrier or diluent further comprising an anti-tumor or anti-cancer agent which is different from 1,3- dihydro- 5,6-dimethoxy-3 - [(4-hydroxyphenyl)methylene]-2H-indol-2-one.

3. The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: There is no special technical feature in the instant claim set.

Independent instant claim 19 discloses a pharmaceutical composition of 1,3-dihydro-5,6-dimethoxy-3- [(4 hydroxyphenyl)methylene]-2H- indol-2-one or a pharmaceutically acceptable salt thereof in combination with a pharmaceutically acceptable carrier, excipient or diluent. Lanzi et al. ("Inhibition of Transforming Activity of the ret/ptc1 Oncoprotein by a 1-Indolinone Derivative," 2000, Int. J. Cancer, Issue 85, Pages 384-390) disclose a pharmaceutical composition of 1,3-dihydro-5,6-dimethoxy-3- [(4 hydroxyphenyl)methylene]-2H- indol-2-one (page 384, under Abstract, lines 8-10 and under Chemicals, lines 1-2) and DMSO (page 384, under Chemicals, last three lines). Therefore, the instant claims do not have a special technical feature and thus the claims lack unity.

Applicant is required to elect a group to be examined on the merits.

Applicant is advised that to be complete, the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103 (a) of the other invention.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph S. Kudla whose telephone number is (571) 270-3288. The examiner can normally be reached on 9am - 5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Joseph S. Kudla/
Examiner, Art Unit 1611
April 29, 2008

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit 1615